

WHAT IS CLAIMED IS:

Sub A1 5
1. A method for treating hyperplasia in a subject in need thereof, said method comprising administering to said subject an effective amount of a composition comprising drug and protein.

2. A method according to claim 1 wherein said drug is in nanoparticle form and is dispersed in said protein.

10 3. A method according to claim 1 wherein said hyperplasia occurs in blood vessel neointima.

15 4. A method according to claim 1 wherein said effective amount falls in the range of about 0.01 mg/kg up to about 15 mg/kg for a human subject.

15 5. A method according to claim 4 wherein said administration of said composition is repeated over a dosing cycle between 1 day and 6 months.

20 6. A method according to claim 1 wherein said composition is administered systemically.

7. A method according to claim 6 wherein administration is accomplished intra-arterially, intravenously, by inhalation, or orally.

25 8. A method according to claim 1 wherein said composition is administered before, during or after the occurrence of said hyperplasia.

Sub A2 30 9. A method for reducing neointimal hyperplasia associated with vascular interventional procedure(s) in a subject in need thereof, said method comprising administering to said subject an effective amount of a composition comprising at least one drug and protein.

10. A method according to claim 9 wherein said procedure comprises angioplasty, stenting or atherectomy.

11. A method according to claim 9 wherein said composition is administered before, during or after the vascular interventional procedure.

12. A method according to claim 9 wherein said composition is administered at 5 the time of the vascular interventional procedure.

13. A method according to claim 9 wherein said effective amount falls in the range of about 0.01 mg/kg up to about 15 mg/kg for a human subject.

10 14. A method according to claim 13 wherein said administration of said composition is repeated over a dosing cycle between 1 day and 6 months.

15 15. A method according to claim 9 wherein said composition is administered systemically.

16. A method according to claim 9 wherein said composition is administered by deployment of a stent containing said at least one drug coated thereon.

20 17. A method to reduce proliferation and cell migration in a subject undergoing a vascular interventional procedure, said method comprising systemically administering a formulation comprising a drug that inhibits proliferation and cell migration, and a biocompatible protein to said subject before, during or after said procedure.

25 18. A composition for treatment of hyperplasia, said composition comprising at least one drug and protein.

19. A composition according to claim 18 wherein said at least one drug is in nanoparticle form and is dispersed in said protein.

30 20. A composition according to claim 18 wherein said hyperplasia occurs in blood vessel neointima.

21. A composition according to claim 18 wherein said drug is a taxane or analog or homolog thereof, an epothilone or analog or homolog thereof, or a rapamycin or analog or homolog thereof.

5 22. A composition according to claim 21 wherein said taxane is paclitaxel.

23. A composition according to claim 18 wherein said composition is suitable for systemic administration.

10 24. A composition according to claim 23 wherein administration is accomplished intra-arterially, intravenously, by inhalation, or orally.

15 25. A composition for reducing neointimal hyperplasia associated with vascular interventional procedure(s), said composition comprising at least one drug and protein.

26. A composition according to claim 25 wherein said procedure is angioplasty, stenting or atherectomy.

20 27. A composition according to claim 25 wherein said composition is suitable for systemic administration.

28. A composition according to claim 27 wherein administration is accomplished intra-arterially, intravenously, by inhalation, or orally.

25 29. A method to reduce the toxicity of a drug that inhibits proliferation and migration of cells, said method comprising combining said drug with a biocompatible protein.

30 30. A pharmaceutical formulation with reduced toxicity, said formulation comprising a drug that inhibits proliferation and cell migration, and a biocompatible protein.